PATENT

Attorney Docket No. LRM-33657

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Mark G. Fleischhacker

Serial No.

09/770,342

Filing Date

January 26, 2001

For

Non-Metallic Guidewire

Confirmation No.

6291

Group Unit

3736

Examiner

Charles Alan Marmor, II

Customer No.

56080

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

I hereby certify that, on the date shown below, this correspondence is being:

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Date: April 4, 2006.

Commissioner for Patents P.O. Box 1450

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DECLARATION OF WILLIAM WHEALON UNDER 37 C.F.R. § 1.132

COMES NOW William Whealon who declares and says as follows:

- I am an employee of Lake Region Manufacturing, Inc. ("Lake Region"), owner 1. by assignment of the subject patent application by the inventor, Mark Fleischhacker. I have the title of Principal Engineer. I hold the degrees of B.S., M.S. and Ph.D. in Materials Science and Engineering, having received those degrees from the University of Wisconsin-Madison.
- Part of my responsibilities as an employee of Lake Region relate to matters of 2. intellectual property, specifically development and enhancement of the company's patent

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portfolio. In pursuit of those duties I have become familiar with, and have examined in some detail, the prosecution history and the references cited in the subject patent application.

3. I have reviewed the Examiner's Action mailed from the Patent and Trademark Office on October 4, 2005. Specifically, I have reviewed the assertions of paragraph 7, page 4 of the Examiner's Action in which the Hurtak reference, U.S. 6,458,088, is indicated to be the basis for a § 102(b) anticipation rejection of claims 1-11 and 16, 17. The statement is made that:

The guide wire (1) includes a core wire (5) formed of a non-metallic, non-woven glass body.... Glass may be considered a polymeric material in a broad sense since it is formed by a mixture of compounds."

4. It is my opinion that one skilled in the art would not understand that glass is a polymer. As we discussed during our phone conference on March 31, 2006, glass is amorphous, while polymers have repeating monomer units which provide significant, repeated structure. There are numerous other differences, all of which suggest that the above assertion is not correct. For example, Hawley's Condensed Chemical Dictionary, 14 ed. (2001) defines glass as follows:

A ceramic material consisting of a uniformly dispersed mixture of silica (sand) (75%), soda ash (20%) and line (5%), often combined with such metallic oxides as those of calcium, lead, lithium, cerium, etc. depending on the specific properties desired. The blend (or "melt") is heated to fusion temperature...and then gradually cooled (annealed) to a rigid, friable state, often referred to as vitreous. Technically, glass is an amorphous, undercooled liquid of extremely high viscosity that has all the appearances of a solid....

5. During the phone conference on March 31, 2006, we discussed an article prepared by the Department of Polymer Science, University of Southern Mississippi (copy attached) in which the question "Is Glass a Polymer" was addressed. The answer, found on page 2 of 3 about 2/3 of the way down, "So is [glass] a polymer or not? Usually it isn't considered as such."

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- 6. I agree with this opinion based upon my knowledge and experience in the field of material science. Glass is commonly thought of as being inorganic having an amorphous non-ordered atomic structure formed by supercooling a liquid. In contrast, polymers are thought of as being organic materials having atoms ordered in chain structure. Polymers are formed by the polymerization of multiple monomers.
- 7. I note that the Amendment to which the present Declaration is attached has several claim amendments directed, in part, to U.S. 5,251,640 ("Osborne"). It should be noted, first of all, that every guide wire disclosed by Osborne requires "helically-wound fibers 13 and 14" (column 2, line 51) or some reasonable equivalent thereof (cf., "a plurality of fibers 62...grouped together to define a band which is itself helically wound about a central axis 61.") (column 3, line 57).
- 8. As is discussed by Mr. Fleischhacker at paragraph 0023 of his Patent Application Publication 2003-0060731 (Page 8 of the Disclosure, line 22), Osborne has a significant drawback. Specifically, the distal segment of the guide wire structure of Osborne et al. cannot be made more flexible by reducing its diameter using the technique of centerless grinding. Clearly, any structure with the counterwound helices or interwoven fibers of Osborne as an exterior layer of the guide wire if centerless ground, would create fractured fibers or helices. This observation is underscored by the fact that Osborne suggests at column 3, line 18, that "the taper of central core 20 is achieved by including several composite fibers 22 of staggered lengths that are bunched together and embedded in epoxy matrix 23." Essentially foreshortening the core wire fibers would be a time-consuming, inexact and expensive method to provide distal tip flexibility as compared to centerless grinding which could be used with the present invention.

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I hereby declare that all statements made herein of my own knowledge are true 9. and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1002 of Fitle 18 of the United States Code.

FURTHER, the Declarant sayeth manght.

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Kaywords: amorphous, crystal

We talk about glass from time to time when we're discussing polymers, especially when we're talking about <u>composite</u> <u>materials</u>. Glass <u>fibers</u> are often used to reinforce polymers. But what is this stuff called glass? We use it with polymers a lot, obviously, but is glass itself a polymer?

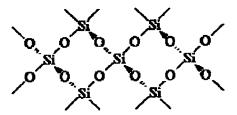
Before we tackle that question, let's take a look at what glass is. The highest quelity glass has the chemical formula SIO₂. But this is misleading. That formula conjures up Ideas of little silicon dioxide molecules, analogous to carbon dioxide molecules. But little silicon dioxide molecules don't exist.

CO₂, carbon dioxide is made up of molecules that look like this.

But SiO₂ malecules like this just plain dan't exist.

Instead, in nature $8iO_2$ is often found as a crystalline solid, with a structure like you see on your right. Every silicon atom is bonded four oxygen atoms, tetrahedrally, of course; and every oxygen atom is bonded to two silicon atoms. When $8iO_2$ is in this crystalline form we call it aidea. You've seen silica before. When you find big honkin' crystals of it we call it quartz. When we have a lot of little tiny crystals of it, we call it sand.

But this silica isn't glass. We have to do something to it first to make it into glass. We have to heat it up until it melts, and then cool it down really fast. When it melts, the silicon and oxygen atoms break out of their crystal structure. If we cooled it down slowly, the atoms would slowly line back up into their crystalline arrangement as they slowed down. (Remember, heat is really just the random motion of atoms and molecules. Hot atoms move a lot, cold atoms move very little.)



SiO₂ in it's crystalline form, quarte

But if we cool it down fast enough, the atoms of the silica will be stopped in their tracks, so to speak. They won't have time to line up, and they'll be stuck in any old arrangement. They'll look something like this:

http://psic.ws/mactest/glass.htm

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is Glass a Polymer?

As you can see, there is no order to the arrangement of the atoms. We call materials like this amorphous. This is the glass that is used for telescope lenses and such things, it has very good optical properties, but it's brittle. For everyday uses, we need something tougher. Most glass is made from sand, and when we melt down the sand, we usually add some sodium carbonate. This gives us a tougher glass with a structure that looks like this:

sodium carbonate

This is the glass you see everyday, in Jars and windows, and it's the glass that's used in composites.

So is this a polymer or not? Usually it isn't considered as such. Why? Some may say it's inorganic, and polymers are usually organic. But there are many inorganic polymers out there. For example, what about polysiloxanes? These linear, and yes, inorganic materials have a structure very similar to glass, and they're considered polymers. Take a look at a polysiloxane:

So glass could be considered a highly <u>crosslinked</u> polysiloxane. But we usually don't think of it that way. Why not? Probably because even in a highly crosslinked system, you could still trace a polymer chain and see where the crosslinks are. But with glass, it'd be tough to do that.



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